K132491

JUN 30 2014

510 (k) SUMMARY

This summary of 510(k) safety and effectiveness is submitted in accordance with the requirements of 21 CRF 807.92

510(k) Number:	K132491
Submitter:	Edge Biologicals, Inc. 598 N 2nd Street Memphis, Tennessee 38105
Contact Person:	Ted Pearson Telephone: 901-523-0034 Fax: 901-527-3343 E-mail: pearson@edgebiological.com
Date Prepared:	May 30, 2014
Trade Name:	Mueller Hinton Agar
Common Name:	Mueller Hinton Agar
Device Class:	II
Classification Name:	21 CFR 866.1700 Culture Medium for Antimicrobial Susceptibility Tests Product Code – JTZ
Predicate Device:	Mueller Hinton Agar with 5% Sheep Blood Becton Dickinson (K960420)

510(k) Summary:

Mueller Hinton Agar is a standard basal medium intended for *in vitro* antimicrobial disk diffusion susceptibility testing of isolated colonies of common, rapidly growing bacteria

by the Bauer-Kirby method standardized by the Clinical and Laboratory Standards Institute (CLSI). This product has not been evaluated for gradient diffusion testing.

The Bauer-Kirby procedure is based on the diffusion through an agar gel of antimicrobial substances which are impregnated on sterile paper disks. This method employs disks with a single concentration of antimicrobial agent and zone sizes are correlated with minimum inhibitory concentrations. In the test procedure, a standardized suspension of the organism is swabbed over the entire surface of the agar medium. Sterile paper disks impregnated with specified amounts of antibiotic or other antimicrobial agents are then placed on the surface of the inoculated agar medium. The agar medium is incubated at 35± 2°C for 16-18 hours. The organism will grow as a solid "lawn". The antimicrobial will diffuse outward (in a circle). If the antimicrobial agent has activity against the organism, a circular zone of growth inhibition will result. The zone of inhibition around the paper disk is measured. A determination as to whether the organism is susceptible, intermediate or resistant to the antimicrobial agent is determined by comparing the size of the zone of inhibition to the zone diameter interpretive criteria in the CLSI M100 Standard.

Summary of Substantial Equivalence Testing:

Mueller Hinton Agar was evaluated in a multi-site reproducibility study. Antimicrobial disk diffusion susceptibility testing was conducted, according to the CLSI *Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard, M02-A11, Vol. 32, No. 1* at three sites, on three separate days. Six bacterial strains representing Gram negative and Gram positive rapidly growing (non-fastidious) CLSI recommended quality control organisms from American Type Culture Collection (ATCC) were included in the study (*Escherichia coli* ATCC 25922, *Staphylococcus aureus* ATCC 25923, *Pseudomonas aeruginosa* ATCC 27853, *Enterococcus faecalis* ATCC 29212, *Enterococcus faecalis* ATCC 51299, and *Escherichia coli* ATCC 35218). Antimicrobials representing the major drug classes relevant to each organism were included in the study. Testing was conducted in duplicate using two different lots of Mueller Hinton Agar, and antimicrobial disks from two different manufacturers, resulting in a total of 72 results for most organism-antimicrobial combinations. Antimicrobial disks from only one manufacturer were available at the time of testing for Cefepime, Ceftaroline, High Level Gentamicin, High Level Streptomycin, resulting in a total of 36 results for each of these antimicrobials.

The performance of Mueller Hinton Agar was evaluated relative to the acceptable range as indicated in the antimicrobial specific FDA drug label, or CLSI Standards M100-S24 or M02-A11. Acceptable performance for each organism-antimicrobial combination was determined as test results falling within the acceptable range ≥95% of the time.

Escherichia coli ATCC 25922 was tested against 14 antimicrobials. A total of three results were out of expected range. The percent of results within expected range was 99.7% (969/972).

Staphylococcus aureus ATCC 25923 was tested against 10 antimicrobials. A total of four results were out of expected range. The percent of results within expected range was 99.4% (644/648).

Pseudomonas aeruginosa ATCC 27853 was tested against seven antimicrobials. One result was out of expected range. The percent of results within expected range was 99.8% (467/468).

Enterococcus faecalis ATCC 29212 was tested against one antimicrobial. The percent of results within expected range was 100%(72/72).

Enterococcus faecalis ATCC 51299 was tested against three antimicrobials. The percent of results within expected range was 100% (144/144).

Escherichia coli ATCC 35218 was tested against five antimicrobials. The percent of results within expected range was 100% (360/360).

The levels of thymine and thymidine in Mueller Hinton Agar were evaluated by testing *Enterococcus faecalis* ATCC 29212 with trimethoprim/sulfamethoxazole. Excess amounts of thymine and thymidine can reverse the inhibitory effect of sulfonamides and trimethoprim, resulting in smaller, less distinct zones of inhibition or no zones at all. The results of the testing of this organism-antimicrobial combination were within range, indicating adequate levels of thymine and thymidine.

The levels of the cations calcium and magnesium in Mueller Hinton Agar were evaluated by testing *Pseudomonas aeruginosa* ATCC 27853 with the aminoglycosides gentamicin and tobramycin. Excess cation content results in reduced zone sizes, whereas low cation content results in unacceptably large zone sizes. The results of the testing of these antimicrobials were within range, indicating adequate levels of calcium and magnesium.

The results of the study for each organism-antimicrobial combination, were within acceptable range ≥95% of the time. This demonstrates that Mueller Hinton Agar is substantially equivalent to similar medium already in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

EDGE BIOLOGICALS, INCORPORATED
TED PEARSON
QUALITY ASSURANCE DIRECTOR
589 N 2ND STREET
MEMPHIS TN 38105

June 30, 2014

Re: K132491
Trade/Device Name: Mueller Hinton Agar
Regulation Number: 21 CFR 866.1700
Regulation Name: Culture medium for antimicrobial susceptibility tests
Regulatory Class: II
Product Code: JTZ
Dated: June 12, 2014
Received: June 13, 2014

Dear Mr. Pearson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally A. Hojvat
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132491

Device Name: Mueller Hinton Agar

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Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Ribhi Shawar -S
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